UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al. ex rel.* ADAM HART, Plaintiffs, v. MCKESSON CORPORATION *et al.,* Defendants.	Civil Action 15 Civ. 0903 (RA)

RELATOR'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE COMPLAINT

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INTRODUCTION

Relator's Amended Complaint ("Complaint") provides a detailed account of Defendants' ("McKesson's") illegal kickback scheme that caused the submission of false claims to Medicare and Medicaid. It alleges that McKesson provided valuable tools to physician practices to induce them to purchase drugs from McKesson, and that McKesson routinely touted the value of those free tools. It alleges that McKesson was fully aware of its illegal kickback scheme, made the kickbacks at issue the centerpiece of its sales strategy, and induced physician practices to purchase drugs from McKesson as a result. The Complaint further provides information about specific customers who received McKesson's kickbacks and submitted claims to Medicare for reimbursement for specific drugs that McKesson sold, during specific time periods.

McKesson's motion to dismiss ignores these well-pled allegations. Effectively conceding that it has no argument on the merits, McKesson instead seeks to change the facts by relying on extrinsic evidence that cannot be considered on a motion to dismiss. Compounding that error, McKesson also advocates the wrong legal standards at every step of its argument. It argues that Relator has not alleged that McKesson's kickbacks meet a heightened "substantial and independent value" standard found nowhere in governing law, asserts that Relator has failed to satisfy an Anti-Kickback Statute (AKS) specific-intent standard that Congress abrogated in 2010, and seeks to impose upon Relator a false-claim pleading standard explicitly rejected by the very case on which McKesson relies.

In short, McKesson wishes to defend a different case than the one pled, under different legal standards than apply here. But McKesson does not have the option to rewrite Relator's allegations or the law. Applying governing law to Relator's claims, the Complaint clearly states a claim under the False Claims Act (FCA).

FACTUAL BACKGROUND

This case concerns McKesson's illegal kickback scheme for cancer drugs it sells to community oncology practices. Congress passed the AKS "to prevent kickbacks from influencing the provision of services that are charged to Medicare" — specifically, to "protect the Medicare and Medicaid programs from increased costs and abusive practices resulting from provider decisions that are based on self-interest rather than cost, quality of care or necessity of services." *United States v. Patel*, 778 F.3d 607, 612, 616-17 (7th Cir. 2015) (internal quotation marks and emphasis omitted). What McKesson did here is precisely what Congress aimed to prevent: it induced physicians to purchase drugs from McKesson, rather than from a competitor, by offering illegal kickbacks. Those kickbacks came in the form of free access to proprietary and admittedly value-added business management tools called the Margin Analyzer and Regimen Profiler, which analyzed how physician groups could maximize profits through their prescribing decisions. Compl. ¶ 49.

I. THE MARGIN ANALYZER

The Margin Analyzer is a tool that analyzes the financial consequences of a community oncology practice's drug-prescription decisions within categories of "therapeutically interchangeable" drugs — *i.e.*, drugs that can be readily substituted for one another. *E.g. id.* ¶¶ 54, 59. It analyzes a practice's historical prescription patterns, forecasts future profits under a different mix of therapeutically interchangeable prescriptions, and guides practices on an insurer-by-insurer basis (including Medicare and private carriers) to the drugs that would be most profitable for the practice — even if that makes the drugs costlier for patients and for the government. *Id.* ¶ 61. The Margin Analyzer does not compare different drugs' clinical effectiveness, side effects, or medical suitability. *Id.* ¶ 6. Rather, the Margin Analyzer "only purports to compare '[c]linically equivalent drugs . . . against each other to observe which

products make the most *financial* sense.'" *Id.* ¶ 63 (emphasis added). As an illustration, the Margin Analyzer that McKesson provided to Summit Cancer Care for the third quarter of 2012 suggested switching to Aloxi for all of the anti-nausea drugs (which are common in treating cancer) that Summit administered. Making that switch would increase the practice's profits from these drugs by 800%, but would increase the government's spending by 2200% and Medicare patients' copays per dose from $0.49 to $46.10. *Id.* ¶ 76. The Margin Analyzer says nothing about whether Aloxi (or any other drug) would best suit patient needs.

The Margin Analyzer compiles a wealth of valuable data and provides a comprehensive financial analysis of recipients' drug prescription practices, including, among other things:

- The current Medicare reimbursement rates for individual cancer drugs, including drugs that the physician practice did not purchase or prescribe, set by the Center for Medicare and Medicaid Services (CMS) on a quarterly basis. *Id.* ¶¶ 42, 56.
- The practice's drug purchasing history and wholesale costs. *Id.* ¶ 57.
- Drug reimbursement rates for private insurers. *Id.* ¶ 58.
- The practice's profit margins and revenues from various drug manufacturers, payer sources, and specific or categories of drugs. *Id.* Ex. 1 at 2-3.
- Forecasts of how the practice's profits could improve by changing which drugs it prescribes to patients with different insurers, including Medicare. *Id.* Ex. 1 at 6.

If McKesson did not offer the Margin Analyzer for free, practices would be required to use their own employees or consultants to obtain and analyze this information, at their own expense. *Id.* ¶¶ 50, 101, 110. McKesson's training materials encouraged its salespeople to tell practices that McKesson could act as a free "consultant" "that can help them increase profit," but only if they committed to purchase a majority of their drugs from McKesson. *Id.* ¶ 64.

The Margin Analyzer held real value for the practices that received it, as McKesson acknowledged repeatedly. *Id.* McKesson made the Margin Analyzer the centerpiece of its sales

efforts, and marketed the Margin Analyzer to oncology practices by emphasizing that it provides "valuable information for optimizing revenue opportunities." *Id.* ¶¶ 102, 104, 107. It referred to the Margin Analyzer (and the Regimen Profiler) as "value added services." *Id.* ¶ 106. Customer testimonials curated into a video by McKesson explained at length how important the Margin Analyzer was to oncology practices' profitability and their "business side," and that it provided value independent of the drugs McKesson sold. *Id.* ¶ 109.

A different division of McKesson's business, the U.S. Oncology Network (USON), sold access to the Margin Analyzer to physician practices as part of a bundled suite of practice-management services, demonstrating its value. *Id.* ¶ 105. However, McKesson's "open market" division — the division at issue in this case — offered the Margin Analyzer to customers solely as an illegal kickback. Practices could get access to the Margin Analyzer for free, but only "in exchange for an agreement to purchase a substantial percentage of their pharmaceuticals from McKesson." *Id.* ¶¶ 3, 69. McKesson used access to the Margin Analyzer as a way both to obtain new customers and to prevent existing customers from moving their business to McKesson's competitors, while avoiding competition on price. *Id.* ¶¶ 61, 64. When an oncology practice informed McKesson that it "intended to end its purchase commitment," McKesson threatened to deny the practice access to the Margin Analyzer. *Id.* ¶ 70.

II. THE REGIMEN PROFILER

The Regimen Profiler is a similar tool that provides data on the profitability of an entire course of treatment for a patient, rather than the profitability of specific drugs. *Id.* ¶ 96. Medicare typically reimburses oncology practices for their efforts in administering drugs as well as for the cost of the drugs. *Id.* ¶ 97. Accordingly, even when a drug may not offer the highest margins compared to alternatives, a practice may be able to maximize profits by prescribing that drug (instead of therapeutically interchangeable alternatives) if Medicare offers high enough

reimbursement rates for attendant services. *Id.* ¶ 100 & Ex. 3. The Regimen Profiler considers those ancillary reimbursements as well as the staffing and overhead costs, the number of treatment cycles needed, the length of each treatment cycle, and other information. *Id.* ¶ 99. Its ultimate output compares the financial effects of "different yet clinically equivalent" treatment regimes, allowing the practice group to maximize its profit without regard to the out-of-pocket costs borne by the patient or the government. *Id.* ¶ 100.

McKesson's open market division limited access to the Regimen Profiler to those practices that contractually committed to purchase substantial volumes of drugs from McKesson. *Id.* ¶ 101. Those practices received access to the Regimen Profiler free of charge, as an express term of their purchasing contracts. *Id.* As with the Margin Analyzer, McKesson's separate USON division sold access to the Regimen Profiler as part of its practice-management services suite, demonstrating the value of the Regimen Profiler. *Id.* ¶ 105.

McKesson and its customers routinely touted the enormous value that the Regimen Profiler provided to oncology practices. McKesson boasted that "Oncology clinics place a premium on McKesson's value-added services," including the Regimen Profiler. *Id.* Ex. 8 at 64. Customers agreed, stating that the Regimen Profiler, along with Margin Analyzer, offered "a whole lot more" than the drugs McKesson sold, and was a "powerful" and "great tool[]." *Id.* ¶ 109. One practice said it was profitable "entirely" because of those tools. *Id.* Others informed McKesson that the Regimen Profiler was a "key component[] of their decision to commit to buying specialty drugs from McKesson." *Id.* ¶ 71. This free access to the Regimen Profiler allowed practices to avoid paying a consultant for the same services. *Id.* ¶ 101.

III. MCKESSON'S ILLEGAL KICKBACK SCHEME

McKesson's kickback scheme was simple. It offered the Margin Analyzer and the Regimen Profiler to physician practices as an explicit *quid pro quo* for the practices'

commitment to buy a substantial majority of their drugs from McKesson. *Id.* ¶¶ 69, 101. It was also hugely successful for McKesson: these "critical sales tools," as McKesson recognized, "resulted in significant purchasing commitments" from practices. *Id.* ¶ 108. McKesson ultimately determined that the Margin Analyzer was "the single most important, and most valuable, tool for McKesson to win new business and maintain its existing customers." *Id.* ¶ 107; *see also id.* ¶ 106 (Margin Analyzer and Regimen Profiler offered "distinct 'competitive advantage' in the market"). At a four-day sales meeting involving the National Sales Vice President and an outside consultant, McKesson's Business Development Executives were trained on how to frame their sales pitch around these valuable tools that differentiated McKesson from competitors. *Id.* ¶ 107.

McKesson's physician group customers — including several identified in the Complaint, *id.* ¶ 53 — routinely submitted claims for reimbursement to Medicare and Medicaid after receiving the Margin Analyzer and the Regimen Profiler as a kickback, *id.* ¶ 121. Indeed, each quarterly Margin Analyzer estimates how many doses of each drug were billed to Medicare by a particular practice in the preceding quarter. *See*, *e.g.*, *id.* Ex. 1 at 5-12. Those claims submitted to Medicare were not eligible for reimbursement because of McKesson's illegal kickbacks, and thus violated the AKS and the FCA. *Id.* ¶ 123.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When evaluating a motion to dismiss, the Court must "construe the complaint liberally, accepting all factual allegations in the complaint as true, and drawing all reasonable inferences in the plaintiff's favor." *Elias v. Rolling Stone LLC*, 872 F.3d 97, 104 (2d Cir. 2017).

ARGUMENT

I. THE COMPLAINT ADEQUATELY ALLEGES THAT THE MARGIN ANALYZER AND REGIMEN PROFILER ARE PROHIBITED "REMUNERATION"

A. Relator's Allegations Satisfy the Statutory Definition of Remuneration

The AKS creates a straightforward prohibition against "offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). The only exceptions to that prohibition are the "safe harbors" defined by statute or regulation, *see id.* § 1320a-7b(b)(3), which "are affirmative defenses on which [defendant] would bear the burden of proof at trial." *United States v. Coloplast Corp.*, 2016 WL 4483869, at *1 n.2 (D. Mass. Aug. 24, 2016).[1] A claim for government reimbursement made in violation of the AKS is false or fraudulent as a matter of law under the FCA. *See* 42 U.S.C. § 1320a-7b(g).

The AKS defines "remuneration" to mean any "transfer[] of items or services for free or for other than fair market value." *Id.* § 1320a-7a(i)(6). Courts applying this expansive definition have concluded that it encompasses "anything of value." *United States v. Narco Freedom, Inc.*,

[1] McKesson's suggestion in a footnote (at 1 n.1) that it has "significant commercial speech defenses under the First Amendment" is not properly presented to the Court. *See Zurich Am. Ins. Co. v. ABM Indus., Inc.*, 397 F.3d 158, 172 (2d Cir. 2005) (an argument made in a footnote in motion papers is not "sufficiently raise[d]"). Even if McKesson had properly raised the argument, it would still fail on the merits. That is because the AKS "regulates only economic conduct. It chills no constitutional rights." *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995). "[I]t has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949).

95 F. Supp. 3d 747, 756 (S.D.N.Y. 2015) (quoting *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 678 (N.D. Ill. 2006)); *State v. MedImmune, Inc.*, 342 F. Supp. 3d 544, 552 (S.D.N.Y. 2018).

The Margin Analyzer and Regimen Profiler are illegal kickbacks under the plain language of the AKS. The Complaint pleads that these concededly "value-added" business tools, Compl. ¶ 106 & Ex. 8 at 55, 60, constitute something "of value," and were selectively provided to oncology practices for free. *See*, *e.g.*, *id.* ¶¶ 64 (Margin Analyzer "can be used to increase practice group revenues while reducing administrative costs"), 109 (Regimen Profiler is a "great tool[]" for the "business side" of a medical practice). A different McKesson division sold access to them, confirming their substantial value. *Id.* ¶ 105. And McKesson instructed its salespeople to emphasize the value of the Margin Analyzer and Regimen Profiler to customers in their sales pitches, calling it the most important and most valuable tool McKesson had for winning and maintaining customers. *Id.* ¶ 107. A sales executive who failed to highlight these value-added services in his sales pitch was fired, highlighting the premium that senior McKesson officials placed on these value-added goods. *Id.*

McKesson's customers also acknowledged the value of these tools. *Id.* ¶ 109. They made commitments to purchase drugs from McKesson based on these kickbacks, and reported that these tools increased their profitability. *Id.* ¶¶ 70-71, 106-07. Occasionally, they even sought, unsuccessfully, to pay for continued access to them after ceasing to purchase drugs from McKesson, a request customers would not make if the tools had no value. *Id.* ¶ 70. Any of those facts alone would be sufficient to show that these tools had value; taken together, they leave room for no other conclusion.

B. McKesson Misstates the Applicable Legal Standard for Determining What Is "Remuneration" and Relies on Impermissible Extrinsic Evidence

Because the Complaint alleges that McKesson's tools have value, the Court need not address McKesson's further arguments on this point. Nonetheless, those arguments lack merit. McKesson asks (at 8-9) this Court to infer an implicit, uncodified safe harbor for kickbacks that "relate to" the products being sold and that lack "substantial and independent" value, based on ten advisory opinions from the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") and (to a lesser extent) one OIG guidance document. This argument must fail because, as a matter of law, OIG advisory opinions and guidance cannot create exceptions to the AKS. Moreover, the guidance itself refutes McKesson's position.

1. OIG Advisory Opinions Are Not Authority the Court May Rely Upon, and in Any Event Do Not Support the Legal Standard McKesson Advances

McKesson's reliance on OIG advisory opinions is misplaced. By statute, HHS can create AKS safe harbors *only* by issuing formal regulations through notice-and-comment rulemaking. *See* 42 U.S.C. § 1320a-7b(b)(3)(E); *id*. § 1320a-7d(a). In recognition of this strict requirement, HHS regulations provide that advisory opinions "will have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion." 42 C.F.R. § 1008.53. Indeed, advisory opinions cannot even be cited "by a person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate the provisions of [the AKS] or any other law." *Id.* § 1008.55(b).[2]

[2] The OIG advisory opinions that McKesson cites amplify this point. Each contains a lengthy disclaimer explaining, among other things, that it: (1) has "no application to, and cannot be relied upon by, any . . . individual or entity" other than the requestor; (2) "may not be introduced

Every court that has considered these statutory and regulatory limitations has concluded correctly that OIG advisory opinions are not authority for anything. *See*, *e.g.*, *United States v. Choudhry*, 262 F. Supp. 3d 1299, 1308 (M.D. Fla. 2017) (OIG advisory opinion was "no authority" for whether a practice violates the AKS); *United States ex rel. Banigan v. Organon USA Inc.*, 2016 WL 10704126, at *4 (D. Mass. Aug. 23, 2016) (refusing to consider OIG advisory opinion); *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, 36 F. Supp. 3d 773, 780 (S.D. Ohio 2014) (rejecting party's reliance on OIG advisory opinions); *Hericks v. Lincare Inc.*, 2014 WL 1225660, at *12 (E.D. Pa. Mar. 25, 2014) (same); *United States v. Abad*, 2013 WL 5718729, at *3 (N.D. Cal. Oct. 21, 2013) (rejecting defendant's reliance on OIG advisory opinion in motion to dismiss indictment); *Klaczak*, 458 F. Supp. 2d at 685-86 (rejecting argument that rationale in advisory opinion applied to similar conduct).

The cases cited by McKesson are not to the contrary. None of them considers the statutory and regulatory provisions that preclude reliance on OIG opinions and prohibit HHS from creating exceptions to the AKS other than by regulation.[3] They are therefore "not authority or precedent" on that issue. *Alli-Balogun v. United States*, 281 F.3d 362, 370 n.7 (2d Cir. 2002).

But even if the Court were to consider OIG advisory opinions, those opinions do not actually support the legal standard advanced by McKesson. OIG advisory opinions frequently

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into evidence" to prove that anyone other than the requestor did not commit a violation; (3) "has no applicability to other arrangements, even those which appear similar in nature and scope"; and (4) expresses "[n]o opinion . . . regarding the liability of any party under the False Claims Act." *See*, *e.g.*, OIG Adv. Op. No. 08-06, 2008 WL 6067516, at *5 (May 2, 2008).

[3] *United States ex rel. Suarez v. AbbVie Inc.*, 2019 WL 4749967 (N.D. Ill. Sept. 30, 2019), does not acknowledge these legal restrictions or explain why they would not apply. The court made clear that OIG guidance "is not binding law," but considered it only because both parties had relied on the guidance and thereby offered a "concession that it is authoritative for purposes of this motion." *Id.* at *6. *Health Choice Alliance, LLC ex rel. U.S. v. Eli Lilly & Co.*, 2018 WL 4026986, at *17 (E.D. Tex. Jul. 25, 2018) similarly failed to address the statutes and regulations that preclude reliance on OIG advisory opinions.

address two questions: (1) whether the proposed arrangement would or might violate the AKS and (2) if so, whether the OIG would exercise its prosecutorial discretion not to impose an administrative sanction for the arrangement in that instance. McKesson misunderstands this distinction. In eight of the ten advisory opinions it cites, including six for which McKesson incorrectly asserts that the OIG concluded there was *not* an AKS violation, the OIG actually determined that the arrangement at issue *did or could* (based on facts unknown to the OIG) constitute prohibited remuneration, but that for policy reasons the arrangement did not warrant an administrative sanction.[4] These exercises of prosecutorial discretion do not suggest that

[4] For clarity, the eight opinions are numbered below. The first six are those for which McKesson misstates OIG's conclusions:

(1) *Compare* OIG Adv. Op. No. 00-10, 2000 WL 35747420, at *5 (Dec. 15, 2000) (reimbursement support services "implicate[] the Federal anti-kickback statute" and "confer an independent financial benefit upon referring physicians"), *with* Mem. at 10 (arguing that OIG found these services "did not constitute prohibited reimbursement").

(2) *Compare* OIG Adv. Op. No. 07-16, 2007 WL 6400843, at *1, *4 (Dec. 5, 2007) (educational videos "could potentially generate prohibited remuneration" but OIG "[l]ack[ed] conclusive evidence" whether the videos represent items of nominal value), *with* Mem. at 18 (arguing that OIG found the videos "did not implicate the AKS").

(3), (4), and (5) *Compare* OIG Adv. Op. No. 10-04, 2010 WL 1937992, at *1-*4 (Apr. 30, 2010) ("[W]e conclude that . . . the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute . . . ."), OIG Adv. Op. No. 10-20, 2010 WL 3897164, at *1-*3 (Sept. 21, 2010) (same), *and* OIG Adv. Op. No. 12-10, 2012 WL 4753657, at *1, *5 (Aug. 23, 2012) (same), *with* Mem. at 14 n.10 (arguing that OIG found that the arrangements at issue "did not implicate the AKS" or "did not constitute prohibited remuneration").

(6) *Compare* OIG Adv. Op. No. 12-19, 2012 WL 7148095, at *1-*2 (Nov. 30, 2012) (free, unlimited access to web-based software "could potentially generate prohibited remuneration under the anti-kickback statute"), *with* Mem. at 18 (arguing that OIG found that "AKS was not implicated" by offering that software).

(7) OIG Adv. Op. No. 08-06, 2008 WL 6067516, at *1 (laboratory pre-labeling test tubes at no charge "could potentially generate prohibited remuneration under the anti-kickback statute" and OIG "could potentially impose administrative sanctions" for it).

McKesson's value-added business services cannot constitute illegal kickbacks; if anything, they demonstrate the breadth of the AKS's prohibitions.

Moreover, the OIG opinions refute McKesson's argument that a free service "related to" the good being sold necessarily lacks "independent value" and therefore is not "remuneration." The OIG repeatedly has found that free services that are inextricably related to the goods or services sold can nonetheless violate the AKS.[5] OIG advisory opinions use the concept of "independent value" merely to frame the question of whether a free service is so "integral" to the product being sold that it should be treated as part of the product itself, rather than as something separate. *See*, *e.g.*, OIG Adv. Op. No. 12-20, 2012 WL 7148096, at *2 (Dec. 12, 2012) ("the OIG has distinguished between free items and services that are integrally related to the offering provider's or supplier's services and those that are not"). "Integral" does not mean merely "related to," as McKesson suggests; it means essential to the whole.[6] For this reason, in all of

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(8) OIG Adv. Op. No. 16-09, 2016 WL 5852763, at *1 (Sept. 16, 2016) (installation of computerized vaccine storage and dispensing system in physician's office "could potentially generate prohibited remuneration under the anti-kickback statute").

[5] *See* OIG Adv. Op. No. 16-12, 2016 WL 7155861, at *1, *4 (Nov. 28, 2016) (pre-labeling of containers that could only be used with kickback provider's laboratory services "would be a tangible benefit" to recipients and therefore constituted remuneration); OIG Adv. Op. No. 08-06, 2008 WL 6067516, at *2, *3 (same); OIG Adv. Op. No. 12-10, 2012 WL 4753657, at *3 (pre-authorization services used in connection with a kickback provider's imaging services would constitute remuneration if they relieved customers of costs or burdens); OIG Adv. Op. No. 10-20, 2010 WL 3897164, at *3 (same); OIG Adv. Op. No. 06-16, 2006 WL 6252287, at *1-*3 (Oct. 3, 2006) (advertising assistance and call center to be used only in connection with kickback provider's products constituted remuneration); OIG Adv. Op. No. 00-10, 2000 WL 35747420, at *5 (pre-qualification services to be used only in connection with kickback provider's products would have "confer[red] an independent financial benefit" on recipients, and therefore "implicate[d]" the AKS). In each of these opinions, OIG found that proposed arrangements did or could violate the AKS even though they were "related to" the goods or services being sold, although in some instances OIG stated that it would exercise its prosecutorial discretion not to impose an administrative sanction.

[6] For example, a laboratory test is useless unless the physician can get the results. *See* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg.

the OIG advisory opinions McKesson cites, the OIG only found three instances where free goods or services lack "independent value." And in each of those, the offeror had merely proposed a novel way of delivering a service that it already provided (or was required to provide) as part of the underlying product sold.[7]

2. OIG Guidance Is Not Binding and Also Fails To Support the Legal Standard McKesson Advances

McKesson also relies (at 13, 18-19) on the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers, which states that "[s]tanding alone, services that have no substantial independent value to the purchaser *may* not implicate the anti-kickback statute." 68 Fed. Reg. 23,731, 23,735 (May 5, 2003) ("2003 Guidance"). The 2003 Guidance is not a regulation; rather, it is a set of hortatory best practices for pharmaceutical companies to use in designing internal compliance programs. As the cases cited by McKesson make clear, the 2003 Guidance also "does not constitute binding law" and cannot create a safe harbor for an AKS violation; at most it is persuasive authority. *United States ex. rel Forney v. Medtronic, Inc.*, 2017 WL 2653568, at *4 n.2 (E.D. Pa. June 19, 2017); *see also* 42 U.S.C. § 1320a-7b(b)(3)(E); *id.* § 1320a-7d(a).

In any event, the 2003 Guidance does not support the legal standard McKesson advances. It expressly describes "[e]xamples of remuneration in connection with a sale" that would "potentially implicate[]" the AKS. 68 Fed. Reg. at 23,736. Those examples include both

35,952-01 at 35,978 (July 29, 1991) (offer of computer terminal incapable of doing anything other than delivering test results would lack independent value).

[7] *See* OIG Adv. Op. No. 12-20, 2012 WL 7148096, at *1, *3 (electronic transmission of orders and results for lab tests lacked value independent of lab tests themselves); OIG Adv. Op. No. 12-19, 2012 WL 7148095, at *4, *8 (software functions for ordering prescriptions and communicating with pharmacy about prescriptions lacked value independent of the drugs sold); OIG Adv. Op. No. 08-20, 2008 WL 6067530, at *4 (Nov. 19, 2008) (provision of on-site staff to comply with offeror's obligations under CMS quality guidelines lacked independent value).

providing "other free … goods or services," and making "[s]elective offers of remuneration (i.e, offers made to some but not all purchasers) . . . if the selection criteria relate directly or indirectly to the volume or value of business generated." *Id.* That is precisely what McKesson did here. It provided free "value-added" business services, and it selectively offered them only to customers that promised to purchase the majority of their drugs from McKesson. *See supra* pp. 2-5.

The cases cited by McKesson are not to the contrary. In *Forney*, the court determined that the relator had not sufficiently alleged "that the free services saved the [customers] money" and therefore had not pled that the alleged kickback had value under *any* standard. 2017 WL 2653568, at *4.[8] When the relator filed a subsequent amended complaint correcting that pleading deficiency, the court denied the defendant's motion to dismiss. *See United States ex rel. Forney v. Medtronic, Inc.*, 327 F. Supp. 3d 831, 836 (E.D. Pa. 2018). Here, the Complaint alleges with particularity that the Margin Analyzer and Regimen Profiler saved "the [customers] money" since these were services that the customers would otherwise need to hire a consultant to perform or separately purchase. Compl. ¶¶ 50, 64, 101, 110. Indeed, a separate business unit sold these "value added" business services as part of a bundled package. *Id.* ¶ 105.

Suarez is similarly inapposite. There, the relator alleged that defendant offered patients free "training on self-injections, assistance with insurance coverage, and answering administrative questions" to induce providers to purchase the drug Humira. 2019 WL 4749967 at *6. The court emphasized that any "goods or services" that "eliminate an expense that the physician would have otherwise incurred" would constitute a violation of the AKS. *Id*. (internal quotation marks omitted). Unlike the complaint here, the *Suarez* complaint failed to plead that

[8] The *Forney* court did rely upon the 2003 Guidance as persuasive authority, but made clear that it "does not constitute binding law." *Id.* at *4 n.2.

these services did so. *Compare id.* at *8 (holding that the relator "pleads no factual content to support the conclusory allegation that physicians and their staff must 'otherwise … perform[]' the services just discussed") (citation omitted) *with* Compl. ¶ 105 ("McKesson divisions outside of the 'open market' division actually do earn revenue by selling [the Margin Analyzer and Regimen Profiler] to physician practices."); *see also id.* ¶¶ 50, 101, 110 (McKesson's tools helped practices avoid having to pay consultants or employees for similar analyses). Moreover, the defendant in *Suarez* had offered the free services to *all* physicians who prescribed Humira for FDA-approved purposes. 2019 WL 4749967, at *2. Thus, the Court had no occasion to examine the portion of the 2003 Guidance discussing the "[s]elective offers of remuneration . . . relat[ing] directly or indirectly to the volume or value of business generated," discussed above. 68 Fed. Reg. at 23,736. The Complaint here alleges that the Margin Analyzer and Regimen Profiler were not provided to *all* McKesson customers; they were selectively offered to only those customers that committed to purchase a majority of their drugs from McKesson. Thus, these free business services could not possibly be considered "integral" to the sale of McKesson drugs: if they were, McKesson would have included them with every purchase.

3. Although Unnecessary, Relator Has Pled "Substantial and Independent" Value

Even if OIG guidance and advisory opinions were applicable, and even if they created the "substantial and independent value" standard that McKesson advocates, nothing McKesson has cited casts any doubt on the sufficiency of Relator's allegations.

As to "independent" value, the Margin Analyzer's and Regimen Profiler's extensive analysis and advice concerning the business consequences of different drug prescription and treatment regimen decisions cannot be considered "integral" to the drugs themselves. Customers can order, administer, and be reimbursed for each of McKesson's drugs without the aid of these

business-analysis tools. Indeed, customers that refused to commit to buying the majority of their drugs from McKesson still made purchases, without receiving either tool. Moreover, McKesson described the tools as "value-added" (*i.e.*, their value was "added" to the value of the drugs McKesson sold) and prepared a promotional video in which customers emphasized that Margin Analyzer and Regimen Profiler provided value entirely independent of McKesson's drug sales. Compl. ¶ 109, Ex. 8 at 55, 60. And at least one customer offered to pay for continued access to those tools even after ceasing its purchases from McKesson. *Id.* ¶ 70. These allegations all demonstrate that the tools' value was independent of McKesson's wholesale offerings.

As to "substantial" value, the materials cited by McKesson (at 8) merely state that remuneration should have greater than "nominal" value, *i.e.*, "more than $10 per item, or $50 in the aggregate on an annual basis," OIG Adv. Op. No. 07-16, 2007 WL 6400843, at *3 (internal quotation marks omitted). The allegations in the Complaint are more than sufficient to show that the Margin Analyzer and Regimen Profiler are worth more than $50 per year. *See supra* pp.2-5.

4. McKesson Impermissibly Relies on Extrinsic Evidence

Recognizing that the Complaint adequately pleads substantial and independent value, McKesson asks the Court to take judicial notice of and rely upon extrinsic evidence that it claims contradicts those well-pled allegations. That is improper as a matter of law.

McKesson cites authority (at 14-15 n.11) for the proposition that information on "a party's official website" can be considered on a motion to dismiss where there is no factual dispute as to the contents. But 15 of the 16 exhibits McKesson attaches to its brief come from *non-party* websites, *see* Exs. B-P to Decl. of E. Solomon (ECF 53-2 to 53-16), and McKesson asks the Court to draw contested factual conclusions therefrom. "[R]eliance on evidence that is not integral to the Complaint — such as declarations or third-party websites — is improper on a motion to dismiss . . . unless the Court converts the motion to one for summary judgment . . . ."

Geebro v. BPR 4000 LLC, 2019 WL 652595, at *1 (S.D.N.Y. Feb. 15, 2019) (citing *Goel v. Bunge, Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016)). That is particularly true where, as here, McKesson offers this extrinsic evidence not "to determine what the documents stated," but rather in an attempt to "prove the truth of their contents." *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007). The Court should disregard all of it.[9]

II. THE COMPLAINT ADEQUATELY ALLEGES THAT MCKESSON ACTED KNOWINGLY AND WILLFULLY

McKesson argues (at 20-22) that Relator has failed to allege that McKesson acted "knowingly and willfully." This argument relies upon McKesson's mistaken assertion (at 20) that the AKS "requires a showing that the company knew its conduct was unlawful." But this specific-intent standard was eliminated by statute in 2010.

[9] None of the extrinsic evidence even supports McKesson's position. The portion of McKesson's website attached as Exhibit A states that the Regimen Profiler offers providers "[v]aluable" information, and a "capability unparalleled in the marketplace," specifically refuting its attorneys' suggestion (at 14-18) that this value-added business tool is worthless, that competitors offered comparable products, and that similar tools are "available publicly." The other 15 exhibits fare no better. McKesson claims (at 15-17) that tools by four non-parties are allegedly comparable to McKesson's Margin Analyzer and Regimen Profiler. *See* Solomon Decl. Exs. B, C, D, E, L, M. But none of these tools calculate the potential profits that "clinically interchangeable" drugs or regimens offer to practice groups. Rather, they are intended for *patients* to help them understand the differences between *non*-interchangeable therapies they may receive. McKesson's reliance (at 16-18) on examples of tools offered by its competitors, *see id.* Exs. G-I, J-K, N-O, is likewise misplaced, because these competitors *do not give out their tools for free* like McKesson does. *See id.* Exs. H, K, N (offering only "demo[s]"/"demonstration[s]" or "diagnostic[s]" for prospective customers who have not paid to access the tools). The fact that other competitors charge for tools potentially comparable to the Margin Analyzer and Regimen Profiler only reinforces that they are valuable. McKesson implicitly asks the court to reject the well-pled allegations in the complaint and to make factual findings before discovery that are not even arguably supported by the documents, including that third-party tools were comparable to McKesson's tools, available for the entire time period covered by Relator's Complaint, and necessarily eliminated all value for McKesson's tools. That is improper. The Court has no need to wade into any of these contested factual issues because they are irrelevant on a motion to dismiss.

A. Relator's Complaint Satisfies the Correct Intent Standard

The AKS prohibits an entity from "knowingly and willfully" offering remuneration in connection with a good or service that will be reimbursed by a federal program (*i.e.*, Medicare). 42 U.S.C. § 1320a-7b(b)(2). Pursuant to a provision added in 2010, "a person need not have actual knowledge of this section or specific intent to commit a violation of this section." *Id.* § 1320a-7b(h) (added by Pub. L. 111-148, 124 Stat. 119, 759 (Mar. 23, 2010)). Rather, under this amended language, Relator is required to plead only "that the defendant willfully committed an act that violated the Anti-Kickback Statute." *United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013); *accord United States v. Patel*, 17 F. Supp. 3d 814, 824 (N.D. Ill. 2014) ("[I]t is clear that the Government need not prove that Defendant had actual knowledge of the [AKS] or specific intent to violate it."), *aff'd*, 778 F.3d 607 (7th Cir. 2015).

As the Fifth Circuit explained in *St. Junius*, the statute's intent element distinguishes negligent or accidental conduct, which is innocent, from willful conduct, which is culpable. Thus, the Fifth Circuit held that proof that a defendant "willfully solicited or received money for referring Medicare patients to" a marketing group was sufficient. 739 F.3d at 210. There is no further requirement that the defendant knew her conduct was a violation of the AKS. *See id.*; *see also United States v. Waller*, 2017 WL 2559092, at *5 (S.D. Tex. June 13, 2017), *aff'd*, 741 F. App'x 267 (5th Cir. 2018) (discussing and applying *St. Junius*).[10]

[10] Alternatively, courts have held that it is sufficient — but not necessary — for Relator to allege generally "that 'Defendant knew that federal and state law prohibited their giving or receiving . . . kickbacks.'" *United States ex rel. Pasqua v. Kan-Di-Ki LLC*, 2012 WL 12895229, at *5 (C.D. Cal. June 18, 2012) (citation omitted); *see also United States ex rel. Strunck v. Mallinckrodt Ard LLC*, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020) (holding that, although specific intent is not required, allegations that defendant's "training programs and policies reflected an understanding of the AKS" supported inference of scienter); Fed. R. Civ. P. 9(b) ("Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."). Relator's Complaint offers that allegation and more. *See*, *e.g.*, Compl. ¶¶ 111-12

The Complaint easily clears this bar. It alleges that McKesson deliberately established and promoted its scheme of providing the Margin Analyzer and Regimen Profiler to physician practices for free in exchange for an agreement to purchase a majority of their drugs from McKesson. *See*, *e.g.*, Compl. ¶¶ 69, 101. It further alleges that senior McKesson executives not only knew about this scheme, but they required salespeople to make it the centerpiece of their sales pitch. *Id.* ¶¶ 106-07. Those allegations do not allow the possibility that McKesson somehow established its kickback scheme accidentally. *Cf. United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) ("[T]he giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal . . . such kickbacks are more clearly *malum in se*, rather than *malum prohibitum*."), cited at page 20 of McKesson's memorandum.

B. The Authorities Cited by McKesson Are Inapposite

All but two of the cases cited by McKesson in support of a specific intent requirement either predate the 2010 amendments to the AKS[11] or follow pre-2010 case law without acknowledging the statutory changes enacted in 2010.[12] The 2010 amendment to the AKS abrogates all of those cases. *See* 42 U.S.C. § 1320a-7b(h).

The two remaining cases have no bearing here. In McKesson's principal case, *Gonzalez*

(alleging that McKesson is aware of "federal and State laws and regulations that prohibit it from offering or paying any remuneration to induce the ordering or purchasing of items or services that Medicare, Medicaid, and other government-sponsored health care programs pay for").

[11] *See United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000), *United States v. Bay State Ambulance & Hop. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989), *Klaczak*, 458 F. Supp. 2d at 674, and *United States v. Shaw*, 106 F. Supp. 2d 103, 120 (D. Mass. 2000), cited at pages 21-22 of McKesson's memorandum.

[12] *See United States ex rel. Osheroff v. Tenet Healthcare Corp.*, 2012 WL 2871264, at *8 (S.D. Fla. July 12, 2012) (relying on *Starks*, 157 F.3d at 838), *Forney*, 2017 WL 2653568, at *5 (relying on *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 241 (3d Cir. 2004)), and *Banigan*, 2016 WL 10704126, at *4 (relying on *Bay State Ambulance*, 874 F.2d at 33), cited at pages 20-22 of McKesson's memorandum.

v. Fresenius Medical Care of North America, 689 F.3d 470, 476 (5th Cir. 2012), the Fifth Circuit did not parse the pleading requirements of the AKS's intent requirement. Rather, in affirming a post-trial judgment as a matter of law, it held (as a factual matter) that plaintiff had failed to offer any evidence at trial to show that the defendant had any "intent to induce referrals." *Id.* (internal quotation marks omitted). Here, by contrast, the Complaint contains robust allegations that McKesson intended for its kickbacks to induce physician practices to purchase a majority of their drugs from McKesson – they were only available to physician groups that committed to do so. *See*, *e.g.*, Compl. ¶¶ 69-71, 106-09. And McKesson's final authority, a set of unpublished, unreported jury instructions from *United States v. Reichel*, No. 15-cr-10324-DPW (D. Mass. June 17, 2016) (ECF No. 244), is beside the point. McKesson cites those instructions (and the pre-2010 case *McClatchey*) for the notion that a defendant whose conduct is designed wholly for purposes *other than* inducing referrals to a government-paid program lacks the requisite intent under the AKS. But here, the Complaint alleges that McKesson offered these kickbacks for the express purpose of increasing or maintaining physician practices' purchases of drugs from McKesson that it knew would be reimbursed by Medicare. *E.g.* Compl. ¶¶ 106-09. These allegations are more than sufficient to plead scienter. *See Arnstein v. TEVA Pharms. USA, Inc.*, 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016) ("*Arnstein I*") (plaintiff "need only prove that one purpose of remuneration is to induce a person to [make a purchase] for which payment is made under a federal health care program") (internal quotation marks omitted).

McKesson also argues that "OIG guidance support[ing] McKesson's belief that its services were in fact lawful"—principally advisory opinions—"would negate the necessary scienter." Mem at 22 (citing *Banigan*, 2016 WL 10704126, at *4). But *Banigan* is directly to the contrary. First, *Banigan* specifically recognized that HHS regulations "prohibit [the

defendant] from offering [OIG advisory opinions] as a defense to AKS allegations," and therefore "[r]emov[ed them] from consideration" entirely. 2016 WL 10704126, at *4 (citing 42 C.F.R. § 1008.55(b)). This alone is fatal to McKesson's argument. But further, *Banigan rejected* in the summary judgment context the precise argument that McKesson raises here, holding that, despite uncertain regulatory terrain, a jury "could plausibly find that" the defendant's conduct "was objectively unreasonable." *Banigan*, 2016 WL 10704126, at *4.[13] The same logic applies with even greater force on a motion to dismiss: McKesson cannot rely on the OIG guidance it cites in the first place, but even if it could, the question of whether McKesson actually contemplated OIG guidance at the time it offered its kickbacks, and, if so, whether such reliance absolves it of liability, is an affirmative defense that cannot be resolved until after discovery.

III. THE COMPLAINT SUFFICIENTLY PLEADS THE SUBMISSION OF FALSE CLAIMS UNDER RULE 9(b)

McKesson's final argument (at 22-25) is that the Complaint fails to satisfy Rule 9(b) because it "fails to identify a single false claim." *See also* Mem. at 24 (citing authority "dismissing claims because no particular false claim has been identified"). Once again, McKesson's relies on an incorrect legal standard and ignores Relator's well-pled allegations.

The Second Circuit has explicitly rejected any requirement that a plaintiff plead a "particular false claim." In *United States ex rel. Chorches for Bankruptcy Estate of Fabula v. American Medical Response, Inc.*, 865 F.3d 71 (2d Cir. 2017), the Second Circuit resolved an intra-circuit split among district courts concerning whether such a requirement exists. *See id.* at 89-93. It held that while a relator *may* satisfy its pleading requirements by identifying examples

[13] To be clear, Relator does not concede that there is any regulatory uncertainty. As discussed in Part I.A *supra*, the AKS clearly prohibits providing anything of value to induce any purchase.

of specific false claims, that is not required so long as the relator alleges facts that "support[] a strong inference that false claims were submitted to the government." *Id*. at 85; *see also id.* at 93 ("Rule 9(b) does not require that every *qui tam* complaint provide details of actual bills or invoices submitted to the government," so long as the relator otherwise pleads a "strong inference that [false] claims were indeed submitted"). Relator satisfies this requirement in two ways.

First, the Complaint *does* contain allegations sufficient to identify examples of specific claims. A complaint need not identify claims by invoice number and amount; rather, it is sufficient to state the "who, what, where, when, and why" of the false claim. *See*, *e.g.*, *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 337 (D. Conn. 2004). Relator's Complaint does that for claims submitted by Summit Cancer Care. *See*, *e.g.*, Compl. ¶¶ 53, 72-86 & Exs. 1, 4, 5. The "who" is Summit Cancer Care. *See*, *e.g.*, *id.* ¶ 53. The "what" is claims for drug reimbursement that were tainted by McKesson's kickbacks — in particular, hundreds of doses of Aloxi, Ondansetron, and Zometa, along with dozens of doses each of Xgeva, Procrit, Neupogen, Neulasta, Infed, Eligard, and Enoxaparin, plus single-digit doses of several other drugs. *Id.* ¶ 86 & Ex. 5 at 38-45. The "where" is Summit Cancer Care's office in Savannah, Georgia. *Id.* ¶ 53. The "when" is the fourth quarter of 2012: the Complaint alleges that McKesson provided its kickback tools to Summit Cancer Care during that quarter, *id.* ¶ 53 & Ex. 1, and also attaches as an exhibit the Margin Analyzer that McKesson provided in the first quarter of 2013, which recounts the practice's actual drug purchasing history from the prior quarter, *id.* ¶ 57 & Ex. 5, including prescriptions that were then submitted to Medicare for reimbursement. The "why" is because of McKesson's kickbacks: the claims Summit Cancer Care submitted to Medicare during the fourth quarter of 2012 violated the AKS because McKesson had provided a kickback

in exchange for Summit Cancer Care's continued purchase of McKesson's drugs during that quarter. *Id.* ¶¶ 65, 68-71.[14] McKesson ignores these allegations entirely.

Second, and independently, the Complaint pleads facts raising a strong inference that McKesson caused thousands of false claims to be submitted to Medicare. One way to create such an inference is by demonstrating a "systematic scheme" by a health care provider. *Chorches*, 865 F.3d at 85. That is because "in light of the significant share of [medical services] that are reimbursed by Medicare and Medicaid (as distinct from private insurance), it is highly likely that any systematic scheme for [falsifying claims] will indeed reach the governmental insurers." *Id.* Here, as in *Chorches*, "it is highly implausible to suggest that the resulting records [from such a scheme] were never submitted to the federal government for reimbursement." *Id.*[15]

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[14] *See also Arnstein I*, 2016 WL 750720, at *17 ("[T]he AKS does not require a kick-back scheme to succeed in generating new business (*i.e.*, new patient prescriptions) in order for a violation to have occurred.") (internal quotation marks omitted); *United States ex rel. Arnstein v. Teva Pharms. USA, Inc.*, 2019 WL 1245656, at *23-*24 (S.D.N.Y. Feb. 27, 2019) ("[T]he FCA does not require the kickback to be the 'but for' cause of the prescription. . . . 'It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback.'") (quoting *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018)). This authority refutes McKesson's arguments (at 23, 25) that that Relator must show that a drug was prescribed "because of" McKesson's kickbacks or that the Court must make the "assumptions" "that physicians would make prescription decisions based on the MA and RP tools." No such allegations or assumptions are required.

[15] *See also United States ex rel. Omni Healthcare, Inc. v. McKesson Corp.*, 2019 WL 438357, at *10 (E.D.N.Y. Feb. 4, 2019) ("[Relator] has described how defendants marketed their fraudulent [scheme] to health care providers, identified the six drugs that were part of the scheme, and provided an approximate timeframe. The information that would permit further identification of the false claims is the identity of the healthcare providers who ordered [drugs under the scheme]. This information is within defendants' knowledge. Thus, [Relator] has satisfied the particularity requirement."); *United States ex rel. Bonzani v. United Techs. Corp.*, 2019 WL 5394577, at *5 (D. Conn. Oct. 22, 2019) (applying *Chorches* and concluding that complaint satisfied Rule 9(b) because it alleged that every claim submitted to the government was false). The Complaint likewise alleges that "all claims for government reimbursement submitted by those physician practices [that received the Margin Analyzer or Regimen Profiler for free] are tainted by the AKS violation and thus violate the FCA." Compl. ¶ 105.

Relator's Complaint satisfies Rule 9(b) under this standard as well. Relator has alleged that giving the Margin Analyzer and Regimen Profiler for free to practices that agreed to purchase a majority of their drugs from McKesson was McKesson's uniform practice, done as an express *quid pro quo*, and enforced by senior McKesson executives. *See*, *e.g.,* Compl. ¶¶ 68-70, 106-08. Relator has further alleged that the Margin Analyzer was updated on a quarterly basis in order to incorporate the latest Medicare reimbursement figures from CMS — figures that are only relevant to practices that submit claims to Medicare. *Id.* ¶ 56. Relator has identified specific physician practices that received McKesson's kickbacks and billed Medicare and Medicaid for drugs tainted by those kickbacks. *See*, *e.g.*, *id.* ¶¶ 53, 118-19. Relator has even attached exhibits showing that one practice that received Margin Analyzer as a kickback billed Medicare for a *majority* of the drugs it purchased from McKesson. *Id.* Ex. 1 at 5-13 (Medicare was 55% of Summit Cancer Center's "payer mix"); Ex. 5 at 38-46 (same).

Thus, Relator has adequately pled a scheme resulting in AKS-tainted Medicare claims. As in *Chorches*, it is reasonable to infer that McKesson's other customers billed Medicare for McKesson's drugs as well. And, as in *Chorches*, the Defendants (but not Relator, who lacks access to the relevant documents) can identify which claims are false: McKesson knows exactly which practices received McKesson's kickbacks, and it even knows from each quarterly Margin Analyzer how many doses of each specific drug each practice billed to Medicare during the preceding quarter. Compl. ¶ 56 & Ex. 1.

McKesson also cites (at 23-25) two unpublished circuit-level cases that, it argues, show that a relator is required to identify specific false claims. But McKesson misreads these cases. In *United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244 (2d Cir. 2019), the Second Circuit affirmed the dismissal of a relator's complaint not because it failed to identify a

specific false claim, but because it failed to provide any substantive allegations about what the alleged fraudulent scheme actually was — the relator simply alleged that New York's Medicaid claim process had been "rigged," without any more detail. *See id.* at 248-49 ("[W]e are left to speculate as to the specific design and implementation of a scheme that purportedly defrauded the federal government of more than $14 billion over the course of six years."). Similarly, in *United States ex rel. Nunnally v. West Calcasieu Cameron Hospital*, 519 F. App'x 890 (5th Cir. 2013), the Fifth Circuit affirmed the dismissal of a relator's complaint because that complaint failed to allege any factual details about how the purported scheme actually operated. *See id.* at 894-95 ("Nunnally's complaint merely offers sweeping and conclusory allegations of 'verbal agreements' between [the hospital] and 'various physicians,' without a shred of detail or particularity. . . The complaint does not specify who in particular was involved in this 'agreement,' or how it constituted an illegal kickback."). Here, by contrast, Relator has explained exactly how McKesson's kickback scheme worked, including the specific *quid pro quo* involved, Compl. ¶ 69, the specific McKesson employees who developed and facilitated the scheme, *id.* ¶¶ 52, 107-08, the actual process by which McKesson went about supplying physicians with their kickbacks, *id.* ¶¶ 56-66, and specific physician practices that received the kickbacks, *id.* ¶ 53 — all in addition to alleging how the scheme would ultimately result in false claims to Medicare, *id.* ¶¶ 101, 118-19. That is more than sufficient to satisfy Rule 9(b).

CONCLUSION

McKesson's motion to dismiss should be denied in its entirety.

Dated: November 6, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 6, 2020, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record in this matter who are on the CM/ECF system.

/s/ Andrew C. Shen